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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,360	11/18/2003	Robert J. Thomas	1440.2032-001	6678
21005 7590 10/16/2008 HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133				
EXAMINER				
PATEL, NIHIR B				
ART UNIT		PAPER NUMBER		
3772				
MAIL DATE		DELIVERY MODE		
10/16/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/716,360

**Applicant(s)**

THOMAS ET AL.

**Examiner**

NIHIR PATEL

**Art Unit**

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06.25.2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 14-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed on June 25<sup>th</sup>, 2008 have been fully considered but they are not persuasive. The applicant argues that Raemer there is no source of pressurized air nor suggest measuring concentration of CO<sub>2</sub> in a gas mix delivered to the patient. The applicant further argues that Raemer does not mention use of substantially low concentrations of CO<sub>2</sub>, nor combination of CO<sub>2</sub> at sufficiently low concentrations and pressurized air to form a gas mix for stabilizing breathing. The examiner disagrees with the applicant's arguments. Raemer does provide source of pressurized air (see col. 4 lines 55-67). Raemer does disclose measuring concentration of CO<sub>2</sub> in a gas mix delivered to the patient (see col. 5 lines 5-15). Raemer discloses an apparatus that does provide use of substantially low concentrations of CO<sub>2</sub> and combination of CO<sub>2</sub> at sufficiently low concentrations and pressurized air to form a gas mix for stabilizing breathing (see col. 5 lines 1-35).

### ***Response to Amendment***

2. The examiner acknowledges the amendment filed on June 25<sup>th</sup>, 2008. The amendment comprises amending claim 1.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims **1, 2, 6 and 7** are rejected under 35 U.S.C. 102(b) as being anticipated by Raemer (US 5,320,093).
5. **As to claim 1**, Raemer teaches an apparatus that comprises a source of carbon dioxide (see col. 5 lines 5-30); an assembly **32** for combining pressurized air with substantially low concentrations of the carbon dioxide resulting in a gas mix (see col. 5 lines 10-20); and a patient centric ventilatory space module coupled to the assembly providing the resulting gas mix for inhalation by a given target, the inhalation of the gas mix effecting respiratory stability of the target (see col. 3 lines 50-60; col. 4 lines 10-20).
6. **As to claim 2**, Raemer teaches an apparatus wherein the assembly includes a positive airway pressure module for providing the pressurized air (see col. 4 lines 17-67).
7. **As to claim 6**, Raemer teaches an apparatus wherein at least one of the source, the assembly and the PCVSM is computer processor **50** controlled to modulate concentration of carbon dioxide in the gas mix (see col. 6 lines 66-68; col. 7 lines 1-20).
8. **As to claim 7**, Raemer teaches an apparatus wherein the computer processor modulates concentration of carbon dioxide in the gas mix as a function of any combination of sensed concentration of carbon dioxide in the PCVSM, sensed target state and detected system changes (see col. 7).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims **4, 5, 8, 9, 11, 12 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Raemer (US 5,320,093).

12. **As to claims 8, 9 and 13**, Raemer substantially discloses a method steps of providing a substantially low concentration of carbon dioxide (**see col. 5 lines 5-30**); and combining pressurized air with the carbon dioxide to form a gas mix having a stabilizing effects on breathing (**see col. 5 lines 10-20**), the pressurized air enabling the carbon dioxide at low concentrations in the gas mix to have stabilizing effects on target respiratory systems (**see col. 3 lines 50-60; col. 4 lines 10-20**).

The method steps would have been obvious because they would have resulted from the use of the device of Raemer.

13. **As to claims 4, 5, 11 and 12**, Raemer substantially discloses the claimed invention; see rejection of claims 1 and 8 above, but does not disclose carbon dioxide in the gas mix that is less than 2%. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Raemer's invention by providing carbon dioxide in the gas mix that is less than 2% in order to provide cleanest gas possible, since it has been held that where the

general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

14. Claims **3 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Raemer (US 5,320,093) in view of Pauley (US 5,975,078).

15. **As to claims 3 and 10**, Raemer substantially discloses the claimed invention; see rejection of claim s 1 and 8 above, but does not disclose a PCVSM that includes an incubator, a tent, a facemask, and a nasal cannula. Pauley teaches an apparatus that does provide a PCVSM that includes an incubator, a tent, a facemask, and a nasal cannula (**see figure 1; col. 3 lines 1-5**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Raemer's invention by providing a PCVSM that includes an incubator, a tent, a facemask, and a nasal cannula as taught by Pauley in order to prevent leakage and inhale maximum amount of gas possible.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/  
Examiner, Art Unit 3772

/Patricia Bianco/  
Supervisory Patent Examiner, Art Unit 3772